Express Mail No. EV 913 329 130 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Srivastava	Confirmation No.:	7769
Serial No.:	09/750,972	Art Unit:	1643
Filed:	December 28, 2000	Examiner:	YAEN, Christopher H.
For:	ALPHA (2) MACROGLOBULIN RECEPTOR AS A HEAT SHOCK PROTEIN RECEPTOR AND USES THEREOF	Attorney Docket No:	8449-134-999 (708584-999133)

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)

MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant received a Notice of Allowance dated August 23, 2006 ("the Notice") in connection with the above-identified application. Accompanying the Notice was a Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) which indicated that the patent term adjustment to date is 0 days for the above-identified application.

Applicant hereby respectfully requests reconsideration of the patent term adjustment indicated in the notice of allowance. Specifically, Applicant believes that the total patent term adjustment to date should be 640 days under 37 C.F.R. § 1.703(f).

In support of this request, Applicant submits the following statement of facts pursuant to § 1.705(b).

(i) The correct patent term adjustment calculated under § 1.702(a) is 741 days, which is the sum of 27 days, which is the delay by the Office under §1.702(a)(1), plus 714 days, which is the delay by the Office under §1.702(a)(2). The bases for this adjustment are as follows.

1. Delay by the Office under § 1.702(a)(1): Section 1.702(a)(1) provides that the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to mail at least one of (i) a notification under 35 U.S.C. § 132 or (ii) a notice of allowance under 35 U.S.C. § 151, not later than 14 months after the date on which the application was filed under 35

U.S.C. § 111(a) or fulfilled the requirements of 35 U.S.C. § 371 in an international application.

As acknowledged by the Office in its calculation of Patent Term Adjustment, the Office failed to mail a notification under 35 U.S.C. § 132 within 14 months of the filing date of this application. This application was filed on December 28, 2000. Accordingly, a Section 132 notification was due by February 28, 2002. However, the first Section 132 notification was mailed by the Office on March 27, 2002, which is a delay of 27 days.

2. Delay by the Office under §1.702(a)(2): Section 1.702(a)(2) provides that the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to respond to a reply under 35 U.S.C. §132 or to an appeal taken under 35 U.S.C. § 134 not later than 4 months after the date on which the reply was filed or the appeal was taken.

Applicant submits that the Office failed to respond to a reply under 35 U.S.C. §132 within 4 months after the date on which a reply was filed. Specifically, the Office failed to respond to Applicant's Amendment filed on November 28, 2003 within the 4 month time period required by Section 1.702(a)(2). This period expired on March 28, 2004 and the Office responded to Applicant's Amendment with a non-final Office Action mailed March 13, 2006, which is a delay of 714 days.

In support of these facts, Applicant submits (1) a copy of Applicant's amendment filed on November 28, 2003 (in response to a non-final Office Action dated August 28, 2003) bearing a stamp indicating receipt by the Office on November 28, 2003, enclosed as **EXHIBIT A**; and (2) a copy of the non-final Office Action dated March 13, 2006, indicating on its summary page that it is responsive to Applicant's communication filed on November 28, 2003, enclosed as **EXHIBIT B**.

(ii) the relevant dates as specified as specified in §§ 1.703(a)-(e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) are as follows:

An adjustment is sought under Section 1.703(a)(2); Section 1.703(a) provides that the period of adjustment under § 1.702(a) is the sum of the following periods:

> (1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) or fulfilled the requirements of 35 U.S.C. § 371 and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first; and
>
> (2) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first.

While the patent term adjustment calculated by the Office included the time period under § 1.702(a)(1), the Office neglected to include the time period under § 1.702(a)(2). Thus, Applicant seeks adjustment under § 1.702(a)(2) for the period beginning March 29, 2004 and ending March 13, 2006. Applicant believes that this period consists of 714 days.

Applicant believes that the total period of adjustment due to examination delay under 37 C.F.R. § 1.703(f) is **640 days**, which is sum of the delays by the Office under §§ 1.702(a)(1) and (a)(2) less the delays by Applicant under §1.704. As discussed above, the delays by the Office amount to a total of 741 days, which is the sum of 27 days under §1.702(a)(1) and 714 days under §1.702(a)(2). As discussed in section (iv) below, Applicant believes that the total delays attributable to Applicant amount to 101 days;

(iii) the above-identified application is not subject to a terminal disclaimer; and

(iv) the circumstances during the prosecution of the application that constitute a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in § 1.704 are believed to consist of the following:

1. 9 days due to Applicant's filing of an Information Disclosure Statement on May 8, 2002, which was considered supplemental to Applicant's response filed April 29, 2002; and

2. 92 days due to Applicant's filing of a response to a December 4, 2002 non-final Office Action on June 4, 2003.

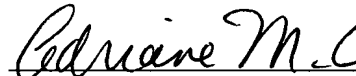
Accordingly, Applicant believes that the delays attributable to Applicant under § 1.704 total 101 days.

In summary, the total adjustment under § 1.702(a) is 741 days, the total delays attributable to Applicant under § 1.704 is 101 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 640 days. Accordingly, Applicant respectfully requests an adjustment of patent term under § 1.703(f) totaling 640 days.

Pursuant to 37 C.F.R. § 1.705(a) and § 1.18(e), the fee required for filing this application is believed to be **$200.00**. Please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: November 16, 2006



32,605

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1642

Express Mail No. EV335858676US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Srivastava et al.	Confirmation No.:	7769
Serial No.:	09/750,972	Art Unit:	1642
Filed:	December 28, 2000	Examiner:	Christopher H. Yaen
For:	ALPHA (2) MACROGLOBULIN RECEPTOR AS A HEAT SHOCK PROTEIN RECEPTOR AND USES THEREOF	Attorney Docket No:	8449-134

AMENDMENT UNDER 37 C.F.R. § 1.111

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated August 28, 2003 and in accordance with Rule 111 of the Rules of Practice, please enter the following amendments and consider the following remarks. Enclosed herewith is Exhibit A: copies of pages 1061-1064, and 1871-1872 of The Merck Manual of Diagnosis and Therapy,1999, Beers and Berkow eds., Merck Research Laboratories, Whitehouse Station N.J.

Amendments to the Specification begin on page 2.

Amendments to the Claims are reflected in the listing of claims which begin on page 3 of this paper.

Remarks begin on page 5 of this paper.

AMENDMENTS TO THE SPECIFICATION:

Please replace the paragraph on page 1, beginning at line 5 with the following paragraph:

This application is a continuation-in-part of application no. 09/668,724 filed September 22, 2000~~.~~ , which ~~This application~~ is a continuation-in-part of ~~co-pending~~ application ~~number~~ no. 09/625,137, filed July 25, 2000, which claims the benefit under 35 U.S.C. § 119(e) ~~to~~ of provisional application no. 60/209,095, filed June 2, 2000, each of which is incorporated by reference herein in its entirety.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-74 (Cancelled).

75 (Currently amended). A method for treating an autoimmune disorder comprising administering to a mammal having an autoimmune disorder an anti-CD91 antibody that binds alpha (2) macroglobulin receptor in an amount effective to treat the autoimmune disorder in the mammal.

76-96 (Cancelled).

97 (Previously amended). The method of claim 75, wherein the antibody interferes with the interaction of the alpha (2) macroglobulin receptor with a heat shock protein.

98 (Cancelled).

99 (Previously amended). The method of claim 97, wherein the heat shock protein is gp96.

100 (Previously amended). The method of claim 97, wherein the heat shock protein is Hsp70.

101 (Previously amended). The method of claim 97, wherein the heat shock protein is Hsp90.

102-110 (Cancelled).

111 (Previously amended). The method of claim 75, wherein the anti-CD91 antibody interferes with the interaction of alpha (2) macroglobulin receptor with an alpha (2) macroglobulin.

112 (Previously amended). The method of claim 111, wherein the autoimmune disorder is selected from the group consisting of: insulin dependent diabetes mellitus, multiple sclerosis, systemic lupus erythematosus, Sjogren's syndrome, scleroderma, polymyositis, chronic

active hepatitis, mixed connective tissue disease, primary biliary cirrhosis, pernicious anemia, autoimmune thyroiditis, idiopathic Addison's disease, vitiligo, gluten-sensitive enteropathy, Graves' disease, myasthenia gravis, autoimmune neutropenia, idiopathic thrombocytopenia purpura, rheumatoid arthritis, cirrhosis, pemphigus vulgaris, autoimmune infertility, Goodpasture's disease, bullous pemphigoid, discoid lupus, ulcerative colitis, or dense deposit disease.

113-121 (Cancelled).

122 (Previously amended). The method of claim 75, 97, 99-101, 111, or 112 wherein the anti-CD91 antibody is an antagonist of the alpha (2) macroglobulin receptor.

123-128 (Cancelled).

129 (Previously amended). The method of any one of claims 75, 97, 99-101, 111, or 112 wherein the mammal is a human.

130-131 (Cancelled).

132 (Previously amended). The method of any one of claims 75, 97, 99-101, or 111, or 112, wherein the antibody is purified.

133-147 (Cancelled).

REMARKS

By this amendment, the specification is amended to correct the language of the priority claim in the first sentence following the title of the instant application. The priority claim was previously entered as an amendment in the transmittal papers filed with the application on December 28, 2000, and is thus timely filed under 37 C.F.R. § 1.78. As such, no new matter has been added by this amendment.

Claims 75, 97, 99-101, 111, 112, 122, 129, 132, and 133-147 were pending in the instant application. By this amendment, claim 75 has been amended and claims 133-147 have been canceled, without prejudice to applicants' right to pursue the canceled claims in other applications. Claim 75 has been amended to indicate that the mammal being treated has an autoimmune disorder. Support for the amendment to claim 75 is found at page 9, lines 33 and 36.

Thus, claims 75, 97, 99-101, 111, 112, 122, 129, and 132 are pending in the instant application. Applicants respectfully request that the amendments and remarks made herein be entered into the record of the instant application.

THE REJECTION UNDER 35 U.S.C. § 102(e), FOR ANTICIPATION, SHOULD BE WITHDRAWN

The Examiner has rejected Claims 75, 97, 99-101, 111, 112, 122, 129, and 132 under 35 U.S.C. §102(e) as allegedly being anticipated by Strickland *et al.* (U.S. Patent No. 6,156,311). Strickland describes the use of an anti-LRP (*i.e.*, an anti-CD91 antibody) for use in treating Alzheimer's disease, which the Examiner contends is a dense deposit disease. Applicants believe that the rejection is in error, for the reasons discussed below.

In order for a reference to anticipate a claim, each and every element of the claim must be disclosed in that one reference. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1985). "Anticipation under Section 102 can be found only if a reference shows exactly what is claimed . . ." *Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707 (Fed. Cir. 1984).

Applicants assert that the claims are not anticipated by Strickland because

Strickland does not disclose methods for use in treating an autoimmune disorder, as the Examiner contends. The Examiner's position is based on the faulty characterization of Alzheimer's disease as dense deposit disease, leading to the erroneous conclusion that because Strickland teaches the use of anti-LRP (*i.e.*, anti-CD91) antibodies to treat Alzheimer's disease, it therefore teaches use of anti-LRP (*i.e.*, anti-CD91) antibodies to treat dense deposit disease, an autoimmune disorder. As discussed in further detail below, Alzheimer's disease is not dense deposit disease, a renal condition and an autoimmune disorder characterized by immune complex deposits in the kidney, but rather a neurological disorder of the central nervous system that is not classified as an autoimmune disorder.

The Examiner contends that, because Alzheimer's disease involves deposits of extracellular plaques, and because the specification has not defined "dense deposit disease," the claims read on the treatment of Alzheimer's disease and thus are anticipated by Strickland. Applicants respectfully disagree. The skilled artisan would clearly understand dense deposit disease to mean a kidney disease caused by deposits in the basement membranes of the kidneys and not Alzheimer's disease. According to the art-recognized reference, The Merck Manual of Diagnosis and Therapy, dense deposit disease is type II membranoproliferative glomerulonephritis, an immune-mediated disorder characterized by chronic immune complex deposition in the glomeruli of the kidneys (see, The Merck Manual of Diagnosis and Therapy, 1999, Beers and Berkow eds., Merck Research Laboratories, Whitehouse Station N.J., pages 1871 and 1872; hereafter "The Merck Manual of Diagnosis and Therapy", submitted herewith as Exhibit A). As described therein, dense deposit disease is characterized by electron dense deposits in the kidney that partially replace lamina densa causing a thickening of the glomerular basement membrane, which are entirely different from the plaque deposits in the brain described by Strickland. Thus, Alzheimer's disease is not dense deposit disease and is not an autoimmune disorder, and does not fall within the scope of the claimed invention.

Moreover, the use of the terms "dense deposit disease" and "Alzheimer's disease" in the specification is entirely consistent with these well established art-recognized definitions. The specification clearly distinguishes between dense deposit disease and Alzheimer's disease. For example, dense deposit disease is characterized in the specification as an autoimmune disorder (see, *e.g.*, page 69, line 29 through page 70, line 1), whereas, in contrast, Alzheimer's disease is distinguished from, and mentioned in the alternative to, an

autoimmune disorder (see, *e.g.*, page 7, lines 33-37; and page 13, lines 12-16). The specification lists an array of diseases which fall within the category of autoimmune disorders, and Alzheimer's disease is not one of them (see, *e.g.*, page 69, line 29 through page 70, line 1). Thus, whereas dense deposit disease is clearly considered an autoimmune disorder both in the art and in the specification, Alzheimer's disease is not considered a dense deposit disease and is not considered an autoimmune disorder, neither in the art as a whole, nor as defined in the specification.

The skilled artisan would not view Strickland as teaching anything regarding autoimmune disease since, at the time of filing of the instant application, Alzheimer's disease was not considered an autoimmune disorder. The Examiner, however, cites Weiner *et al.* (Nature, 2002, 420: 879-884) for the proposition that Alzheimer's disease is now implicated as having "inflammatory and immune components amenable to treatment by anti-inflammatories and immunotherapeutic approaches," presumably implying that Alzheimer's disease is an autoimmune disorder and therefore would fall within the scope of the claimed invention. However, this post-filing date reference does not alter what the skilled artisan would understand reading Strickland at the relevant time, *i.e.*, the filing date of the instant application.

Moreover, Weiner does not disclose or even suggest that Alzheimer's disease is considered an autoimmune disorder. Autoimmune disorders are defined by The Merck Manual of Diagnosis and Therapy as, "[D]isorders in which the immune system produces autoantibodies to an endogeneous antigen, with consequent injury to tissues" (see p. 1061-1064). Clearly, the disclosure that a disease has inflammatory and immune components amenable to treatment by anti-inflammatories and immunotherapeutic approaches does not mean that the disease is an autoimmune disorder. In fact, Weiner specifically distinguishes Alzheimer's disease ("AD") from a true autoimmune disorder, muscular sclerosis ("MS") in the following passage:

> "[A]lthough it has become increasingly recognized that inflammation may be important in the neuropathological damage that occurs in AD, unlike MS the inflammation in AD seems to arise from inside the CNS with little or no involvement of lymphocytes or monocytes beyond their normal surveillance of the brain. The inflammatory cytopathology...is thought to represent a *secondary response* to the early accumulation of Aβ in the brain." (Emphasis added)

Weiner et al. page 882, ¶ abridging first and second columns). Thus, even in view of the disclosure of Weiner, Alzheimer's disease would not be considered an autoimmune disorder. As such, the claimed invention does not encompass Alzheimer's disease.

In summary, Strickland does not disclose all of the elements of the claimed methods for treating an autoimmune disorder. In particular, Strickland does not disclose administering an antibody to a mammal having an autoimmune disorder for treatment of the autoimmune disorder, because Alzheimer's disease is not an autoimmune disorder. Thus, Strickland does not anticipate the claimed methods for treating an autoimmune disorder.

In view of the remarks above, Strickland does not disclose or suggest the claims of the instant invention. Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C.§ 102(b) should be withdrawn.

CONCLUSION

An allowance of the application is earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

Date: November 26, 2003

Adriane M. Antler 32,605
Adriane M. Antler (Reg. No.)

By: Eileen E. Falvey 46,097
Eileen E. Falvey (Reg. No.)

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,972	12/28/2000	Pramod K. Srivastava	8449-134	7769

20583 7590 03/13/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,972	SRIVASTAVA, PRAMOD K.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75,97,99-101,111,112,122,129 and 132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75,97,99-101,111,122,129 and 132* is/are rejected.

7)☒ Claim(s) *112* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: Srivastava P.K.

The amendment filed 11/28/2003 is acknowledged and entered into the record.

Accordingly, claims 1-74,76-96,98,102-110,113-121,123-128,130-131, and 133-147 are canceled without prejudice or disclaimer.

Claims 75,97,99-101,111-112,122,129, and 132 are pending and examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The Information Disclosure Statement filed 7/9/2004 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 102

The rejection of claims 75,97,99-101,111,122,129, and 132 as being anticipated by Strickland *et al* (US Patent 6,156,311) as evidenced by Weiner *et al,* Singh (Gerontology 1997;43:79-94), and D'Andrea MR (Med. Hypotheses. 2005;64(3):458-463) under 35 USC § 102(e) is maintained for the reasons of record. Applicant argues the that claims of the instant invention are not anticipated by Strickland *et al.* Specifically, applicant argues that Strickland *et al* do not teach nor disclose a method of treating an autoimmune disorder. Applicant further contends that the examiner has

mischaracterized the term dense deposit disease as being equivalent to Alzheimer's disease (AD). Applicant supports this assertion by referencing the Merck Manual citing passages that characterize dense deposit disease as being a disease associated with immune complex deposits in the kidney. Applicant further argues that Alzheimer's disease is "not an autoimmune disorder" as defined in the specification or as being an art recognized autoimmune disorder. Applicant further indicates that the specification characterizes Alzheimer's disease as being an alternative to autoimmune disease (applicant points to page 7, lines 33-37 and page 13, lines 12-16). Applicant further argues that those of skill in the art would not have recognized "at the relevant time, i.e. the filing date of the instant application" that Alzheimer's disease was an autoimmune disease in view of the teachings of Weiner *et al.* Applicant further points to the Merck Manual for a definition of autoimmune diseases. Finally applicant concludes that Alzheimer's disease is not encompassed by the instant claims, based on the fact that the claims are drawn to treating autoimmune diseases, of which Alzheimer's is excluded. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). In the instant case, although Alzheimer's disease (AD) was not fully characterized as being an autoimmune disease at the time of the invention (see Singh Gerontology 1997;43:79-

94), subsequent characterizations of the disease indicates that the disease is in fact an autoimmune disease (see D'Andrea MR Med. Hypotheses. 2005;64(3):458-463). Specifically, Singh teaches 5 general characteristics of autoimmunity (see page 82, left column), among these include cell-mediated immunity to auto-antigens and the production of auto-antibodies *in vitro* and *in vivo*. Singh also indicates that cell-mediated immunity may play a role in the induction of autoimmunity (see page 80). Singh specifically indicates that AD is a disease which may involve the $CD8^+$ and $CD4^+$ T-cell arm of the immunoregulatory network (see page 91). Finally, Singh concludes that autoimmune diseases in general are genetically determined and indicates that AD may not be any different (see page 91).

Moreover, others have recently indicated that Alzheimer's disease has characteristics associated with autoimmune disorders. Specifically, D'Andrea teaches that auto-antibodies have been detected in the serum, CSF and in amyloid plaques of patients with AD (see page 459) and have been found to be associated with autoimmunity-induced cell death (see abstract). Therefore, Alzheimer's disease, although not fully characterized as being an autoimmune disease at the time of the invention, has been associated or characterized as being a disorder involving autoimmunity.

Finally, references cited to show a universal fact need not be available as prior art before applicant's filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. In the instant case, although some of the cited references (i.e. Weiner *et al* and

D'Andrea) are post filing date references, the references are used to show that Alzheimer's disease is inherently an autoimmune diseases and is therefore a scientific truism. Irregardless of whether the disease was characterized as being an autoimmune disease post-filing, the method performed by Strickland *et al* (i.e. the administration of anti-CD91 antibody) would, as now claimed, treat an autoimmune diseases.

Therefore, the rejection of claims under 35 USC 102(e) as being anticipated by Strickland *et al* is maintained for the reasons of record.

Conclusion

Claim 112 is objected to as being dependent on a rejected claim. Consequently, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
February 22, 2006

CHRISTOPHER YAEN
PATENT EXAMINER